

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION**

LAWRENCE E. RUSSELL and
MARY J. RUSSELL,

Plaintiffs,

vs.

HOWMEDICA OSTEONICS CORP.,

Defendant.

No. C06-4078-MWB

**ORDER ON MOTION TO EXCLUDE
TESTIMONY OF MARI S. TRUMAN**

This is a products liability action involving the Xia Spinal System® (“the System”), manufactured by the defendant, Howmedica Osteonics Corp. (“Howmedica”). The System is a “hook, screw, and rod spinal fixation system.” On March 14, 2005, Dr. Ralph Reeder, a Sioux City, Iowa, neurosurgeon, surgically implanted the System into the back of the plaintiff Lawrence E. Russell. Mr. Russell had a history of serious back problems. The System was intended to support Mr. Russell’s back for six months or longer, until his vertebrae could fuse together. Support for his back was provided, in part, by two rods made from commercially pure titanium (“CP Ti”).

About two months after the surgery, Mr. Russell felt a snap in his back, followed by great pain. X-rays established that the right rod had broken. Dr. Reeder performed a second surgery on May 25, 2005, to repair the rod. During the surgery, Dr. Reeder discovered there also was a hairline fracture in the left rod. Dr. Reeder splinted each rod together with titanium alloy rods. Shortly after this surgery, the right CP Ti rod broke again. On June 6, 2005, Dr. Reeder performed a third surgery in which he completely replaced the CP Ti rods with titanium alloy rods. After the third surgery, the titanium alloy rods did not break.

Dr. Reeder believed that all of the rods he placed in Mr. Russell's back during the three surgeries were made from titanium alloy. He did not know the rods he placed in Mr. Russell's back initially were made from CP Ti. Howmedica representatives supplied the rods Dr. Reeder used in Mr. Russell's back.

The plaintiffs allege the System was defectively designed because it used rods made of CP Ti. They claim CP Ti is too weak to handle the loads present in a person of Mr. Russell's size. They also allege Howmedica failed to warn surgeons properly of the dangers of using CP Ti spinal rods in heavier individuals.

The plaintiffs served a timely witness designation identifying Mari S. Truman, a biomechanical engineer, as a liability expert. On January 22, 2008, Howmedica filed a motion (Doc. No. 60) to exclude Ms. Truman's testimony pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) and its progeny. The plaintiffs resisted the motion on February 22, 2008. (Doc. No. 70) Howmedica filed a reply on February 28, 2008. (Doc. No. 71) The court heard telephonic arguments on the motion on March 5, 2008. The plaintiffs were represented by John F. Thomas and Michael Eversden, and Howmedica was represented by Robert M. Connolly, Jeffrey W. Wright, and Erin Guy. The motion is now fully submitted.

Ms. Truman prepared a report dated July 8, 2007, in which she provided the following opinions, which she stated were "within the bounds of reasonable engineering and scientific certainty":

1. The use of CP Ti for Xia spinal rods when used as a posterior fixation device in lumbar or lumbo-sacral fusions is a design defect and a cause of premature rod failures and injury to Mr. Russell.¹

¹During his argument in resistance to the motion, counsel for the plaintiffs clarified that this is a design defect only when the rods are used in persons weighing more than 180 pounds.

2. The combination of notch sensitive material and geometry in the CP Ti Xia spinal rods when used as a posterior fixation device in lumbar or lumbo-sacral fusions is a design defect and a cause of the premature rod failures and injury to Mr. Russell.
3. Howmedica/Stryker/Osteonics failed to properly warn surgeons on use restrictions required to prevent Xia titanium implant overload, and they failed to provide guidance concerning patient activity and weight restrictions required to prevent Xia titanium implant overload when used as a posterior fixation device in lumbar or lumbo-sacral fusions. These omissions are a warnings defect and a cause of the premature rod failures and injury to Mr. Russell.

Plaintiffs' Appendix, Doc. No. 72, p. 192.

Howmedica argues these opinions should be excluded from evidence at trial pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) and its progeny. In *Blakely v. Anesthetix of Iowa, P.C.*, 2006 WL 5097351 (N.D. Iowa Feb. 27, 2006), then Chief Judge Mark W. Bennett set out the principles to be applied when considering such arguments:

[T]he Eighth Circuit Court of Appeals has instructed that: “‘The question of whether expert testimony should be admitted or excluded is a matter governed by federal, rather than state, law.’” *Clark ex rel. Clark v. Heidrick*, 150 F.3d 912, 914 (8th Cir. 1998) (quoting *Fox v. Dannenberg*, 906 F.2d 1253, 1255 (8th Cir. 1990)). Admission of expert testimony is governed by Federal Rule of Evidence 702, which states:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or

education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Federal Rule of Evidence 703, in turn, considers the admissibility of the bases for opinion testimony by experts:

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted. Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect.

Fed. R. Evid. 703. Finally, Federal Rule of Evidence 704(a) provides guidance on when an expert's opinion on an ultimate issue is permissible:

(a) Except as provided in subdivision (b) [which pertains to mental state of a criminal defendant], testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

Fed. R. Evid. 704

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), the United States Supreme Court held that, consistent with the “liberal thrust” of the Federal Rules of Evidence, this rule replaced the more rigid “general acceptance” test of *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923). As the Eighth Circuit Court of Appeals subsequently explained, as interpreted by *Daubert*,

Rule 702 requires the trial judge to act as a “gatekeeper,” admitting expert testimony only if it is both relevant and reliable. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). The trial court is granted broad discretion in its determination of reliability. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999). The gatekeeper role should not, however, invade the province of the jury, whose job it is to decide issues of credibility and to determine the weight that should be accorded evidence, *see Arkwright Mut. Ins. Co. v. Gwinner Oil. Co.*, 125 F.3d 1176, 1183 (8th Cir. 1997). Expert testimony should be admitted if [1] it is based on sufficient facts, [2] it “is the product of reliable principles and methods,” and [3] “the witness has applied the principles and methods reliably to the facts of the case.” Fed. R. Evid. 702; *see also General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997).

United States v. Vesey, 338 F.3d 913, 916-17 (8th Cir. 2003); *Anderson v. Raymond Corp.*, 340 F.3d 520, 523 (8th Cir. 2003) (“Under [*Daubert*], district courts must act as gatekeepers to ‘insure that proffered expert testimony is both relevant and reliable.’”) (quoting *Dancy v. Hyster Co.*, 127 F.3d 649, 652 (8th Cir. 1997), *cert. denied*, 523 U.S. 1004, 118 S. Ct. 1186, 140 L. Ed. 2d 316 (1998)); *Kudabeck v. Kroger Co.*, 338 F.3d 856, 859 (8th Cir. 2003) (“[Rule 702]

consists of three distinct but related requirements: (1) the evidence must be based on scientific, technical or other specialized knowledge that is useful to the finder of fact in deciding the ultimate issue of fact; (2) the witness must have sufficient expertise to assist the trier of fact; and (3) the evidence must be reliable or trustworthy.”).

In *Daubert*, the Supreme Court established how the trial court is to perform its “gatekeeper” function under Rule 702:

First, the trial court must make a “preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” [*Daubert*, 509 U.S.] at 592-93, 113 S. Ct. 2786, 125 L. Ed. 2d 469. The Court cautioned that the trial court must focus “on [the] principles and methodology, not on the conclusions that they generate.” *Id.* at 595, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469. Second, the court must ensure that the proposed expert testimony is relevant and will serve to aid the trier of fact. *Id.* at 592, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469. Expert testimony assists the trier of fact when it provides information beyond the common knowledge of the trier of fact. *Id.* at 591, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469. The Court, in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999), clarified that the district court’s gatekeeper function applies to all expert testimony, not just testimony based in science. *Id.* at 147, 526 U.S. 137, 119 S. Ct. 1167, 143 L. Ed. 2d 238.

Kudabeck, 338 F.3d at 860. However, “[a]s the Supreme Court emphasized in *Daubert*, 509 U.S. at 595-96, ‘Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional

and appropriate means of attacking shaky but admissible evidence.’” *Vesey*, 338 F.3d at 917.

“‘Expert testimony is admissible if it is reliable and will help the jury understand the evidence or decide a fact in issue.’” *Archer Daniels Midland Co. v. Aon Risk Servs., Inc.*, 356 F.3d 850, 858 (8th Cir. 2004) (quoting *Hartley v. Dillard's, Inc.*, 310 F.3d 1054, 1060 (8th Cir. 2002)). “An expert need not have an opinion on an ultimate issue of fact in order for the testimony to be admissible.” *Archer Daniels Midland Co.*, 356 F.3d at 858; see *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001). Doubts regarding the admissibility of expert testimony should be resolved in favor of its admission. See *Clark v. Heidrick*, 150 F.3d 912, 914 (8th Cir. 1998). “As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.” *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995) (citing *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988)); accord *Archer Daniels Midland Co.*, 356 F.3d at 858 (“Generally, the factual basis of an expert's opinion goes to credibility of the testimony, not admissibility.”); *Bonner*, 259 F.3d at 929 (quoting *Hose*, 70 F.3d at 974). The Eighth Circuit Court of Appeals has instructed that: “An expert’s opinion must be excluded only if it ‘is so fundamentally unsupported that it can offer no assistance to the jury.’” *Archer Daniels Midland Co.*, 356 F.3d at 858 (quoting *Bonner*, 259 F.3d at 929-30) (quoting in turn *Hose*, 70 F.3d at 974).

Blakely, 2006 WL 5097351 at *1-*3.

Applying these principles, the court will act as a “gatekeeper,” and will evaluate the proffered testimony of Ms. Truman to ensure that it is both relevant and reliable under the standards set forth in FRE 702 and in *Daubert* and its progeny. At the same time, the court will keep in mind the “liberal thrust” of the Federal Rules of Evidence, and will resolve any doubts in favor of admissibility.

Although Ms. Truman, in her report, breaks her findings down into three separate opinions, for purposes of the plaintiff's claims in this lawsuit, her opinions can be reduced to two. First, she opines that the design of Howmedica's Xia Spinal System® was defective because it used CP Ti rods as fixation devices, and Cp Ti is not an appropriate metal to handle the loads of a person of Mr. Russell's sized. She concludes that this design defect caused the premature failure of the rods inserted into Mr. Russell's back and his injuries. Second, she opines Howmedica failed to warn surgeons properly concerning the proper uses of CP Ti rods and the necessary post-surgical restrictions on patient activity. She concludes that this failure to warn was a cause of the premature failure of the rods inserted into Mr. Russell's back and his injuries. According to Ms. Truman, Howmedica should have advised surgeons not to use CP Ti rods in patients weighing more than 180 pounds, and should have provided surgeons with more guidance concerning necessary restrictions on patient activity after the rods are implanted.

Defective Design

Howmedica argues Ms. Truman should not be permitted to present to the jury her opinion that the System was defective. Pointing to the first requirement of Rule 702, Howmedica argues Ms. Truman's opinion was based on demonstrably insufficient facts and data, and is connected to the data only "by the *ipse dixit* of the expert." Doc. No. 60-2, p. 8 (citing *Pro Service Automatic, L.L.C. v. Lenan Corp.*, 469 F.3d 1210, 1216 (8th Cir. 2006)).

Howmedica claims, "Ms. Truman has offered absolutely no scientific evidence to support her assertion that using CP Ti in spinal rod implants constitutes a design defect." Doc. No. 60-2, p. 9. Howmedica points out "Ms. Truman herself admitted that the 'overwhelming majority of rods being used in the marketplace are made of CP Ti or titanium alloy' and not of stainless steel." *Id.* (citing Def's. App. pp. 103). Howmedica

notes that about 70% of the “hook, screw, and rod spinal fixation systems are manufactured from CP Ti and titanium alloys.” Doc. No. 60-2, p. 9. Howmedica also notes that Dr. Reeder made a “clinical decision” to use titanium spinal rods rather than stainless steel rods. *Id.*

According to Howmedica, CP Ti, titanium alloy, and stainless steel all “have proven biocompatibility.” *Id.* Howmedica argues Ms. Truman has presented no scientific data to support her claim that stainless steel or titanium alloy should have been used on Mr. Russell instead of CP Ti. In fact, according to Howmedica, scientific data shows stainless steel is more susceptible to fretting corrosion, “which could lead to tissue reaction and operative site pain, as well as worsen the fatigue performance of the device.” *Id.* Ms. Truman admitted there are several advantages to using CP Ti, including its compatibility with MRI scans and the fact that its modulus is closer to bone than any other metal. Doc. No. 60-2, pp. 9-10.

HOWMEDICA claims Ms. Truman’s opinion that the use of CP Ti in the System was a design defect is based “purely on speculation,” and is “contrary to the beliefs of Dr. Reeder and the majority of the scientific evidence and the orthopedic medical device industry.” Doc. No. 60-2, p. 10. Howmedica further argues Ms. Truman’s opinion that CP Ti rods should not be implanted in “larger” persons also is unsupported by any scientific evidence or data. According to Howmedica, this is only Dr. Truman’s “subjective opinion.” *Id.* Howmedica also notes that Ms. Truman is critical of the testing methodology created by the American Society for Testing and Materials used by the FDA. Doc. No. 60-2, p. 11.

The plaintiffs respond by pointing out that Rule 702's requirement that an expert opinion be based on sufficient facts or data “is a minimal standard,” citing *Hartley v. Dillard’s, Inc.*, 310 F.3d 1054, 1061 (8th Cir. 2002) (“As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it

is up to the opposing party to examine the factual basis for the opinion in cross-examination.”) Doc. No. 72, p. 11. As factual support for Ms. Truman’s opinions, they cite Mr. Russell’s medical records; the broken implants themselves; photographs of the implants; a metallurgical report prepared by metallurgical engineer Larry Hanke; an article by Jeffrey C. Dick, M.D. and Craig A. Bourgeault, B.S.; and several other documents and articles.

Mr. Hanke’s report has not been challenged by Howmedica. Mr. Hanke examined the three fractured CP Ti rods that were removed from Mr. Russell, and concluded that the failure mechanism for all of them was fatigue fracture. He concluded that prior mechanical damage to the rods’ surfaces was a major factor in the fatigue fracture initiation. Microscopic examination confirmed that the fracture mechanism was fatigue, and the each of the fractures initiated at prior mechanical damage to the rod surface. He noted that CP Ti is a notch-sensitive material that requires extra care to avoid damage during implantation to avoid fatigue fractures. He found no evidence of material flaws in the rods. Pls’ App., pp. 225-26. Mr. Hanke stated, “The rod material, unalloyed titanium, is well known to be very susceptible to fatigue fracture initiation at surface damage,” citing the article by Dick and Bourgeault. He identified this characteristic as “notch sensitivity.” Pls’ App., P. 226. Mr. Hanke stated that titanium alloy is 50% stronger than CP Ti. Pls’ App. p. 248. He further stated, “The design for unalloyed titanium components must account for the notch sensitivity of the material when surface damage is possible and the component will be subjected to cyclical stresses. In addition, adequate instructions for and care in preparing and installing these components is required to avoid fatigue failure due to excessive surface damage.” Pls’ App., p. 225.

The Dick and Bourgeault article, titled “Notch Sensitivity of Titanium Alloy, Commercially Pure Titanium, and Stainless Steel Spinal Implants,” was published in 2001 in Volume 6, Number 15, of “Spine,” an international peer-reviewed journal. The authors

conducted a study to show “the difference in fatigue life of the three rods and the effect on fatigue life of marks caused by techniques unavoidable in spine surgery.” Pls’ App., p. 266. In the study, several rods made of the three materials were stressed after being prepared in different ways. None of the stainless steel rods failed, some of the titanium alloy rods failed, and all of the CP Ti rods failed. The authors noted, “Multiple studies have demonstrated the decrease in fatigue life of [CP Ti and titanium alloy] when the surface of the implant is marked or notched.” *Id.* They further stated that to their knowledge, “the notch sensitivity of [CP Ti and titanium alloy] is not widely appreciated by surgeons, and has not been quantified by the manufacturers or other researchers.” *Id.* The authors observed, “[I]t has long been known that the fatigue life of titanium is significantly decreased by scratches or marks on its surface (notches).” Pls’ App., p. 269. They stated further, “When posterior screw, hook, and rod systems are used, however, the rods are always notched in some way by the connections between the screw or hook and the rod and, if necessary, in bending the rods with *in situ* or French benders.” *Id.*

The authors noted the limitations in their study, stating, “Titanium rod fracture has not yet been a significant clinical problem. Although the four-point bending model is the gold standard for testing this type of construct, the force used was preselected to break any rod weakened in any way. The forces used may have been far greater than those to which these constructs are subjected *in vivo*. However, in clinical use, the force placed on the French bender is greater, enough actually to bend the rod, and the crack caused may be substantially larger and deeper than the crack in this investigation. Larger, deeper cracks may shorten the fatigue life even more.” *Id.*

In addition to the Dick and Bourgeault article, Ms. Truman cited a number of other scholarly articles and reports in support of her opinions. *See, e.g.*, Pls’ App., pp. 163-69, 171-73.

In several areas, the court agrees with Howmedica that it is difficult to find support for Ms. Truman's opinions in the factual record. For example, while the record supports a conclusion that titanium alloy is less likely than CP Ti to fail when fatigued, and stainless steel is even less likely to fail, there is little evidence that establishes when the relative advantages and disadvantages of each material require the use of one of the materials rather than another. There also is little evidence to support the 180-pound cutoff for the use of CP Ti suggested by Ms. Truman. Nevertheless, while there are problems with the factual support for several of Ms. Truman's opinions, the court cannot say these opinions are based on insufficient facts or data for purposes of Rule 702. This is for the jury to sort out.

Howmedica also argues Ms. Truman did not employ or apply reliable principles or methods in reaching her opinions, and therefore her opinions do not satisfy the second and third requirements of Rule 702. Doc. No. 60-2, p. 13. Howmedica notes that other than reviewing Mr. Hanke's report and other reports and articles, Ms. Truman did not perform or request any further testing of the spinal rods removed from Mr. Russell. Howmedica therefore argues Ms. Truman's opinions should be excluded under Rule 702.

This argument is not persuasive. Ms. Truman was entitled to rely on the report of a metallurgical engineer and on published reports and articles.

Finally, Howmedica argues Ms. Truman's testimony should be excluded because it would fail to assist the trier of fact. Doc. No. 60-2, p. 15. In this argument, Howmedica simply states its conclusion that Ms. Truman's opinions would fail to assist the trier of fact, and then supports the argument with a bald statement that Ms. Truman's opinions are not based on sufficient facts or data and are therefore unreliable. This argument is unavailing. The rigorous examination of Ms. Truman's opinions during her testimony will provide information beyond the jury's common knowledge. Her opinions

are relevant, and will assist the jury in determining whether, based on all of the evidence presented at trial, they believe the System was designed defectively.

For these reasons, Howmedica's motion to exclude Ms. Truman's opinion testimony that the Xia Spinal System[®] was designed defectively is **denied**.

Failure to Warn

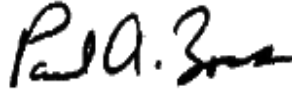
Howmedica also argues Ms. Truman should not be permitted to testify to her opinion that Howmedica failed to warn surgeons properly concerning the proper uses of CP Ti rods. Doc. No. 60-2, p. 11-12. Howmedica claims the warnings suggested by Ms. Truman are commonly known to surgeons from the medical literature. Specifically, Howmedica states Dr. Reeder was aware of the matters contained in the warnings suggested by Ms. Truman, and nevertheless made an informed decision to use CP Ti rods in the surgery on Mr. Russell.

The court disagrees. While Dr. Reeder may have decided that the relative benefits of titanium outweighed the relative benefits of stainless steel, there is evidence in the record to support the plaintiffs' claim that he did not have adequate information to make an informed choice between titanium alloy and CP Ti. There also is evidence to support the plaintiffs' claim that he had insufficient information to advise Mr. Russell properly concerning the specific risks presented by CP Ti. Moreover, the record contains evidence that Dr. Reeder did not even know he was using CP Ti rods in the initial surgery. The motion to exclude Ms. Truman's testimony that there was a failure to warn is denied.

Thus, Howmedica's motion (Doc. No. 60) to exclude Ms. Truman's testimony is denied.

IT IS SO ORDERED.

DATED this 2nd day of April, 2008.

A handwritten signature in black ink, appearing to read "Paul A. Zoss", written over a horizontal line.

PAUL A. ZOSS
CHIEF MAGISTRATE JUDGE
UNITED STATES DISTRICT COURT